From: GROW D1
To: [redacted]
Cc: [redacted]
Subject: RE: Bilateral request for clarification purposes - RE: DIAsource Immunoassays - PFOA
Date: lundi 15 juin 2020 09:52:00
Attachments: image006.png
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image010.gif
image011.gif

Dear [redacted],

Thanks for your message asking for clarifications on the wording of the PFOA exemption for medical devices, as relevant for the products of DIASource Immunoassays.
By way of preliminary matter, let us recall the three pieces of medical devices legislation that apply today, as well as at the time when the PFOA restriction was adopted. They are the following:

- Directive 90/385/EEC on active implantable medical devices
- Directive 93/42/EEC on medical devices
- Directive 98/79/EC on in vitro diagnostic medical devices

The wording of the relevant exemption of Entry 68, point 3(c) admittedly is not crystal clear in itself. What is clear is that it relates to another exemption, namely that of Entry 68, point 4(d)(i). The question is whether point 3(c) is to be understood as exempting any medical devices falling within the scope of any of the above three directives, with the exception of those implantable medical devices within the scope of 93/42/EEC, or whether point 3(c) is to be understood as exempting only medical devices covered by Directive 93/42, with the exception of those that are implantable medical devices within the scope of Directive 93/42/EEC.

In order to interpret the exemption of point 3(c), we went back to the history of both the exemptions of point 3(c) and point 4(d)(i), which is as follows:

1. The original Annex XV report submitted by Germany and Norway did not propose exemptions for medical devices at all.
2. The compiled RAC-SEAC opinion shows that RAC suggested one exemption, without limitation in time, for "implantable medical devices as defined by Council Directive 93/42/EEC". This was the only exemption suggested by RAC. In other words, all other medical devices, no matter which of the above three directives applied to them, would be caught by the restriction.
3. The compiled RAC-SEAC opinion shows that SEAC suggested the same exemption, without limitation in time, for "implantable medical devices as defined by Council Directive 93/42/EEC". In addition, SEAC suggested a time-limited exemption for "non-implantable medical devices (except wheelchairs and dental treatment chairs) for which the transitional period is 15 years" with the motivation that it "seems to be necessary for non-implantable medical devices in order to avoid the situation that some critical applications might not remain available to the healthcare

sector". It is noticeable that SEAC did not refer, or limit, to Directive 93/42/EEC in relation to this time-limited exemption.

4. The compiled RAC-SEAC opinion, page 39, shows that following the public consultation on the Annex XV report, the Dossier Submitter proposed derogation for medical devices until 2020, and for implantable cardiovascular devices until 2030. Again, no reference, or limitation, to Directive 93/42/EEC. This is confirmed in the final Background Document.
5. When the proposal was tabled for discussion in the REACH Committee meeting of October 2016, the Commission's draft text foresaw the exemptions in the same wording as finally adopted, with the reference to Directive 93/42/EEC included. The Detailed Explanation prepared by the Commission in accordance with Article 73(1) stated that "the Commission proposes simply to apply the longer deferral to all non-implantable medical devices".
6. Recital (6) of Regulation 2017/1000 refers to SEAC suggesting longer deferrals of the restriction for, inter alia, non-implantable medical devices, without further qualification.

Based on all the above, we understand the exemption of point 3(c), which was suggested at a later stage than that of point 4(d)(i), as applying to all medical devices that are not exempted under point 4(d)(i), and that the wording "medical devices other than implantable medical devices within the scope of Directive 93/42/EEC" in point 3(c) covers all medical devices that are not "implantable medical devices within the scope of Directive 93/42/EEC" mentioned under point 4(d)(i), regardless in which directive's scope they fall.

We hope you find this explanation useful.
Best Regards,
[redacted]

European Commission
DG Internal Market, Industry, Entrepreneurship and SMEs
[redacted]

From: [redacted]
Sent: Tuesday, May 5, 2020 2:42 PM
To: GROW D1 [redacted]
Cc: [redacted]
Subject: Bilateral request for clarification purposes - RE: DIAsource Immunoassays -

[redacted]

Dear Colleagues,

We get in touch bilaterally in order to lift our misunderstanding, based on the attached Commission answer, relative to the exchange of mail we have had with Diasource.

Indeed, it appears to us that **IVD (In vitro Diagnosis) is a specific legislation distinct from MedDev Dir (MDD)… Therefore, based on the the way the Annex XVII entry on PFOA is phrased, we cannot see how an exemption would apply, at least on this basis.**

We are very well aware that the discussions will take place under POPs Regulation… and the situation might probably evolve very soon… but we still wanted to have a bilateral exchange in order to ensure our correct understanding.

Many thanks in advance and
Best regards,

For [redacted]